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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,851	11/03/2003	Yoh-ichi Matsumoto	019026-000110US	3540
20350	7590	01/06/2009		
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER	
			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			01/06/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/700,851	<b>Applicant(s)</b> MATSUMOTO ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

1) Responsive to communication(s) filed on 06 October 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 5-23,25 and 29-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 5,12,13 and 21 is/are allowed.

6) Claim(s) 6-11,14-20,22,23,25 and 29-33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/GS/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicants' Response to Notice of Noncompliant Amendment, received 6 October 2008, is acknowledged. Claim 7 has been amended.
2. Claims 5-23, 25, and 29-33 are pending and under consideration.

#### **Rejections Withdrawn**

3. The rejection of claims 7-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of the amendment of the claims.

#### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6, 14-20, 22, 23, 25 and 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 14-17 are drawn to any humanized antibody that competes with the mouse antibody deposited as Acc. No. FERM Bp-10877 for binding to VT2.

Claims 18 and 19 are drawn to a method of producing any humanized antibody that competes with the mouse antibody deposited as Acc. No. FERM Bp-10877 for binding to VT2.

Claim 20 is drawn to a composition comprising any humanized antibody that competes with the mouse antibody deposited as Acc. No. FERM Bp-10877 for binding to VT2.

Claim 22, 23, 25, and 29-32 are drawn to a method of treating a patient comprising administering any humanized antibody that competes with the mouse antibody deposited as Acc. No. FERM Bp-10877 for binding to VT2.

Claim 33 is drawn to a cell line that produces any humanized antibody that competes with the mouse antibody deposited as Acc. No. FERM Bp-10877 for binding to VT2.

The specification teaches only a humanized mouse antibody which meets the criterion of claim 6.

Thus, the subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., all humanized antibodies utilizing any species other than mouse.

6. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is drawn to a humanized antibody comprising CDRs from the mouse antibody and heavy and light chain VR frameworks from the human GF4 antibody heavy and light chain frameworks provided that  $\geq 1$  position selected from the group consisting of L49, H29, H30, H49 and H98 is occupied by the amino acid present in the equivalent position of the mouse antibody heavy or light chain variable region framework, which humanized antibody binds to verotoxin II.

The claim refers to amino acid position in the human GF4 antibody heavy and light chain frameworks for determining amino acids present in "equivalent" position of the mouse antibody

heavy or light chain variable region framework. However, there is no reference sequence in the claim for the human GF4 frameworks. Thus, it is unclear, without a SEQ ID NO designation for the human GF4 antibody sequence in the claim, exactly which amino acids are in "equivalent" positions.

Claims 8-10 depend from claim 7, but do not clarify the issue.

7. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a humanized antibody of claim 5 in which various positions in amino acids may be substituted "as shown in Tables 2 and 3".

Because the specification may be amended to change the content of Tables 2 and 3, the scope of the instant claims is unclear as to what is encompassed by the claims. It is recommended that the claim list the possible substitution amino acid residues.

### **Conclusion**

8. Claims 6-11, 14-20, 22, 23, 25 and 29-33 are rejected.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

January 4, 2009